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EDWARD W. BRYANT
U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CRB

JAMES CAMPBELL (SC);
 DAVIS DUTY (AR);
 LAWRENCE HERRICK (WI);
 BENJAMIN HINES (MS);
 ALFRED HOLLEY (SC);
 JERRY WHITAKER (MS);
 CYNTHIA JOHNSON Individually and as the
 Personal Representative of the Estate of
 GREGORY A. JOHNSON (MN)
 Plaintiffs,
 vs.
 PFIZER, INC., PHARMACIA CORPORATION,
 MONSANTO COMPANY and G.D. SEARLE,
 LLC,

Defendants.

Docket No. **07 2530**

CIVIL COMPLAINT

JURY TRIAL DEMANDED

1
2 Plaintiffs, James Campbell, Davis Duty, Lawrence Herrick, Benjamin Hines, Alfred Holley,
3 Jerry Whitaker and Cynthia Johnson Individually and as the Personal Representative of the Estate of
4 Gregory A. Johnson, by and through their counsel, bring this action against Defendants PFIZER, INC.,
5 PHARMACIA CORP., MONSANTO COMPANY, and G.D. SEARLE LLC. (hereinafter collectively
6 “Defendants”) and allege as follows:
7

8
9
10 **I. PARTIES**

11 1. This is an action for damages arising from Defendants’ design, manufacture, sale,
12 testing, marketing, advertising, promotion, and/or distribution of the unsafe medication Celecoxib,
13 trade name CELEBREX® (“CELEBREX”).

14 2. Plaintiff James Campbell was at all relevant times adult resident citizens of the State of
15 South Carolina, County of Beaufort. Plaintiff James Campbell began taking Celebrex on or about
16 March 29, 2000. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe
17 cardiovascular injuries while taking Celebrex, including, but not limited to, a heart attack on or about
18 November 24, 2002, which has caused and will continue to cause Plaintiff damages and places
19 Plaintiff at risk of further serious injury or death.
20

21 3. Plaintiff Davis Duty was at all relevant times adult resident citizens of the State of
22 Arkansas, County of Sebastian. As a direct and proximate result of using CELEBREX, Plaintiff
23 suffered severe cardiovascular injuries while taking Celebrex, including, but not limited to, a heart
24 attack on or about June 17, 2003, which has caused and will continue to cause Plaintiff damages and
25 places Plaintiff at risk of further serious injury or death.
26

27 4. Plaintiff Lawrence Herrick was at all relevant times adult resident citizens of the State
28 of Wisconsin, County of Chippewa. As a direct and proximate result of using CELEBREX, Plaintiff

1 suffered severe cardiovascular injuries while taking Celebrex, including, but not limited to, a heart
2 attack on or about April 20, 2003, which has caused and will continue to cause Plaintiff damages and
3 places Plaintiff at risk of further serious injury or death.
4

5 5. Plaintiff Benjamin Hines was at all relevant times adult resident citizens of the State of
6 Mississippi, County of Washington. As a direct and proximate result of using CELEBREX, Plaintiff
7 suffered severe cardiovascular injuries while taking Celebrex, including, but not limited to, a heart
8 attack on or about January 20, 2002, which has caused and will continue to cause Plaintiff damages
9 and places Plaintiff at risk of further serious injury or death.
10

11 6. Plaintiff Alfred Holley was at all relevant times adult resident citizens of the State of
12 South Carolina, County of Abbeville. As a direct and proximate result of using CELEBREX, Plaintiff
13 suffered severe cardiovascular injuries while taking Celebrex, including, but not limited to, a heart
14 attack on or about September 21, 2001, which has caused and will continue to cause Plaintiff damages
15 and places Plaintiff at risk of further serious injury or death.
16

17 7. Plaintiff Jerry Whitaker was at all relevant times adult resident citizens of the State of
18 Mississippi, County of Monroe. As a direct and proximate result of using CELEBREX, Plaintiff
19 suffered severe cardiovascular injuries while taking Celebrex, including, but not limited to, a heart
20 attack on or about September 8, 2001 which has caused and will continue to cause Plaintiff damages
21 and places Plaintiff at risk of further serious injury or death.
22

23 8. Plaintiff Cynthia Johnson is the wife and personal representative of the estate of
24 Gregory A. Johnson and was at all relevant times adult resident citizens of the State of Minnesota,
25 County of Ramsey. Decedent Gregory A. Johnson began taking Celebrex on or about February 2004.
26 As a direct and proximate result of using CELEBREX, Decedent suffered severe cardiovascular
27 injuries while taking Celebrex including, but not limited to, a heart attack on or around May 30, 2004,
28

1 which resulted in his death.

2 9. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of
3 business in New York, New York. In 2003, Pfizer acquired Pharmacia Corporation for nearly
4 \$60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the
5 business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and
6 selling the drug Celecoxib, under the trade name CELEBREX in California and nationwide.

7
8 10. Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co. ("Searle") is a
9 Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has
10 been engaged in the business of marketing and selling CELEBREX nationwide and in California.
11 Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged within this
12 Complaint.
13

14
15 11. Defendant Monsanto Company ("Monsanto") was the parent corporation of Searle and
16 is a Delaware corporation. At all times relevant hereto, Monsanto, through its subsidiary companies,
17 was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product
18 CELEBREX nationwide.

19
20 12. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its
21 principal place of business in New Jersey. At all relevant times, Pharmacia, and its predecessors in
22 interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing,
23 distributing, promoting, and selling CELEBREX nationwide and in California.

24 **II. JURISDICTION AND VENUE**

25 13. This is an action for damages, which exceeds seventy-five thousand dollars
26 (\$75,000.00).

27 14. There is complete diversity of citizenship between the Plaintiffs and Defendants. This
28 Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity

jurisdiction) because the amount in controversy exceeds \$75,000.00, and because there is complete diversity of citizenship between Plaintiffs and Defendants.

15. Venue is proper in this United States Judicial District pursuant to 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in the district, thereby receiving substantial financial benefit and profits the dangerous product in this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

16. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, CELEBREX. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (including California and Louisiana) the aforementioned prescription drug. Defendants do substantial business in the State of California and within this Federal Judicial District, advertise in this district, receive substantial compensation and profits from sales of CELEBREX in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein each defendant acted as the agent for each of the other defendants, or those defendant's predecessors in interest.

III. INTERDISTRICT ASSIGNMENT

17. Assignment to the San Francisco Division is proper as this action is related to *In Re: Celebrex and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005. (See also, MDL-1699 Pretrial Order No. 2)

IV. FACTUAL BACKGROUND

A. Facts Regarding All Plaintiffs

18. Plaintiffs and Plaintiffs' healthcare providers were at the time of Plaintiffs' injuries

1 unaware - and could not have reasonably known or have learned through reasonable diligence - that
2 such injury directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and
3 misrepresentations or from Plaintiffs' ingestion of CELEBREX.

4 19. Plaintiffs used CELEBREX in a proper and reasonably foreseeable manner and used it
5 in a condition that was substantially the same as the condition in which it was manufactured and sold.

6 20. Plaintiffs would not have used CELEBREX had Defendants properly disclosed the
7 risks associated with the drug.

8 **B. Facts Regarding CELEBREX: Science and other Cox-2 Inhibitors**

9 21. CELEBREX is one of a class of pain medications called non-steroidal anti-
10 inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name
11 Advil) are examples of well-known NSAIDs.

12 22. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes
13 called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and COX-2.
14 Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

15 23. In addition to decreasing inflammation, the prostaglandins that are supported by COX-1
16 enzymes are involved in the production of gastric mucus; this protects the stomach wall from the
17 hydrochloric acid present in the stomach. It is generally accepted in the medical community that by
18 blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and as a result,
19 can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

20 24. Prostaglandin I2 is the predominant cyclooxygenase product in endothelium, inhibiting
21 platelet aggregation (preventing clot formation), causing vasodilation, and preventing the proliferation
22 of vascular smooth muscle. Whereas older NSAIDS inhibit Thromboxane A2 and Prostaglandin I2,
23 the COX-2 inhibitors leave Thromboxane A2 unaffected. Thromboxane A2 is a potent platelet
24 aggregator and vasoconstrictor which is synthesized by platelets. Therefore, while the older NSAIDS
25 suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors support it.

1 25. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by
2 inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional
3 NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood clots,
4 rather they actually reduce the risk of clots and help protect heart function.
5

6 26. Defendants and other pharmaceutical companies set out to remedy these ulcer and
7 bleeding problems suffered by some NSAID users by developing “selective” inhibitors that would
8 block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue
9 while still reducing inflammation.
10

11 27. In making this decision, Defendants and their predecessors in interest either
12 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2
13 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood
14 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,
15 unstable angina. The vasoconstriction and fluid retention cause the hypertension.
16

17 28. Pfizer launched CELEBREX, the first of the three major COX-2 inhibitor drugs, in
18 January 1999 and initiated a massive marketing campaign to convince doctors and consumers of the
19 superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In May, 1999, Merck &
20 Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.
21

22 29. Seeking increased market share in this extremely lucrative market, Defendants, and
23 their predecessors in interest, also sought approval of a “second generation” selective COX-2 inhibitor
24 and filed for FDA approval of Celecoxib (Celebrex) on January 16, 2001 for the (i) prevention and
25 treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief of the signs and
26 symptoms of osteoarthritis and adult rheumatoid arthritis.
27
28

1 **C. Facts Regarding CELEBREX's Safety and Defendants' Knowledge Thereof**

2 30. The potential for cardiovascular risk of selective COX-2 inhibitors was known to
3 Defendants long before the market launch. By 1997, and prior to the submission of the New Drug
4 Application (the "NDA") for CELEBREX, Defendants was aware that, by inhibiting COX-2,
5 CELEBREX altered the homeostatic balance between prostacyclin synthesis and thromboxane and
6 thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those who
7 ingested it. *See* Topol, E.J., *et al.*, *Risk of Cardiovascular Events Associated with Selective Cox-2*
8 *Inhibitors*, *JAMA*, August 22, 2001 at 954.

9
10
11 31. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania, reported
12 in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that it was
13 known as early as 1999 that selective COX-2 inhibitors, such as CELEBREX, suppressed the
14 formation of prostaglandin 1-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may
15 predispose patients to myocardial infarction or thrombotic stroke.

16
17 32. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and basic
18 research on this type of selective inhibitor which had been widely conducted, Defendants knew when
19 CELEBREX was being developed and tested that selective COX-2 inhibitors posed serious
20 cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone
21 with existing heart disease or cardiovascular risk factors. Studies show that selective COX-2
22 inhibitors, including CELEBREX, decrease blood levels of a prostacyclin. When those levels fall, the
23 arteries are more vulnerable to clotting, high blood pressure, heart attack, and stroke.

24
25 33. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new
26 studies specifically analyzing the risks of CELEBREX, Defendants failed to take any action to protect
27 the health and welfare of patients, but instead, continued to promote the drug for sale even after the
28

1 FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory
2 Committee meetings.

3
4 1. **CELEBREX and Cox-2 Studies Did Not Show CELEBREX to be Safe**

5
6 34. The defendants touted the CELEBREX Long-Term Arthritis Safety Study ("CLASS")
7 as the primary evidence to support its theory that CELEBREX was safer for consumers that could not
8 tolerate traditional NSAIDs in their gastrointestinal system. (CLASS data is found in NDA 20-998/S-
9 009 submitted to the FDA by G.D. Searle on June 12, 2000. CLASS was submitted to the FDA on
10 June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20,
11 2000.)

12
13 2. **CLASS**

14
15 35. The FDA Medical Officer Review of the CLASS data proves CELEBREX is no more
16 efficacious than other traditional NSAIDS and is harmful to consumers. See generally, FDA Medical
17 Officer Review, NDA 20-998/S-009 submitted to the FDA by G.D. Searle on June 12, 2000 ("FDA
18 CLASS Review"). On April 7, 2005, the FDA issued an *Alert* noting only minimal information is
19 available regarding CELEBREX: "The only available data from a long term comparison of
20 CELEBREX to other NSAIDs came from the CLASS study...."

21
22 36. Pfizer misrepresented the data in CLASS by using biased authors. According to the
23 *Washington Post* the CLASS authors were either employees of Pharmacia, CELEBREX's
24 manufacturer, or paid consultants of the company. Pfizer needed a study to demonstrate that its Cox-2
25 inhibitor was safer for the stomach than older cheaper medications: CLASS was designed to be that
26 study. Unfortunately, the results of the completed study revealed the truth – CELEBREX offered no
27 gastrointestinal (GI) benefit. Instead of releasing the complete –12-month – results from CLASS,
28

1 Pfizer had only the first six months of data published in the Journal of American Medicine. JAMA
2 2000,48:1455-1460.

3 37. "After reviewing the full study, the FDA's arthritis advisory committee concluded that
4 CELEBREX offers no proven safety advantage over the two older drugs in reducing the risk of ulcer
5 complications, said FDA spokesman Susan Cruzan." *Washington Post*, August 5, 2001. According
6 to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any statistical superiority to
7 NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with regards to the primary safety
8 endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in
9 the trial although there were trends that favored celecoxib" (FDA CLASS Review)
10

11
12 38. According to an August 5, 2001 article in the *Washington Post*, editors of the Journal of
13 the American Medical Association (JAMA) and other medical experts, "were flabbergasted" when
14 they realized they had been duped by only being provided with the first six months of CLASS data.
15 The Washington Post reported JAMA editors as saying: "When all of the data were considered, most
16 of CELEBREX's apparent safety advantage disappeared."
17

18 39. The "scientific double-cross" boosted sales. "[T]he JAMA article and editorial have
19 likely contributed to CELEBREX's huge sales. 'When the JAMA article comes out and confirms the
20 hype, that probably has more impact than our labeling does,' said Robert J. Temple, director of
21 medical policy at the FDA's Center for Drug Evaluation and Research." *Washington Post*, August 5,
22 2001.
23

24 40. "A total of 36 deaths occurred during the [CLASS] study or during post study follow-
25 up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group Most deaths
26 were cardiovascular in nature." FDA CLASS Review, at 54. The increased number of adverse
27 cardiovascular events in the CELEBREX group was not surprising as they were also revealed in the
28

1 original New Drug Application (NDA) submitted for CELEBREX. "In the original NDA, myocardial
2 infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo treated
3 patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate
4 (>90%) cause of death for patients taking celecoxib at any does was cardiovascular." FDA CLASS
5 Review at 78.
6

7 41. Public Citizen, a public watchdog organization, reviewed the CLASS data in its
8 entirety. A complete review reveals the combined anginal adverse events were 1.4% in celecoxib
9 (CELEBREX) group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in the
10 CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.
11

12 42. The CLASS data proves that Pfizer knew that its first generation Cox-2 inhibitor,
13 CELEBREX, caused a disproportionately and statistically significantly high number of adverse
14 cardiovascular events before it was introduced to the market in January 1999. According to Public
15 Citizen, after CLASS, the FDA recommended a trial to specifically assess the CV risk of COX-2
16 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-
17 controlled trial of CELEBREX.
18

19
20 3. **APC Trial**

21 43. The Adenoma Prevention with Celecoxib (APC) trial compared the efficacy and safety
22 of celecoxib with placebo. N.ENG. J. MED. 352;11 at 1072. According to the APC trial, the number of
23 deaths from cardiovascular causes was significantly higher in the CELEBREX group when compared
24 to placebo. (0.1% placebo; 0.4% CELEBREX 200mg; and 0.9% CELEBREX 400mg). *Id.* at 1075.
25
26
27
28

1 44. The FDA Reported the APC data as follows¹:

2
3 In the National Cancer Institute's Adenoma Prevention with Celecoxib
4 (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold
5 increased risk of serious adverse CV events was seen for CELEBREX
6 compared to placebo after a mean duration of treatment of 33 months.
7
8 There appeared to be a dose response relationship, with a hazard ratio of
9 2.5 for CELEBREX 200 mg twice daily and 3.4 CELEBREX 400 mg
10 twice daily for the composite endpoint of death from CV causes,
11 myocardial infarction (MI), or stroke.
12

13 45. The dosage noted in the study is important for two reasons: first, there appears to be an
14 association between dosage and the increase in adverse cardiovascular events. See generally, at 1077.
15 Second, most patients increase dosage. Pfizer knew patients were increasing their dosages as noted in
16 CLASS: "Interestingly ... up to 70% of patients increased their dose for celecoxib." FDA CLASS
17 Review at 74. Thus, Pfizer was aware of the dosage creep.
18

19
20 4. **Other CELEBREX Trials**

21 46. Several other CELEBREX trials also gave Defendants insight into the cardiovascular
22 risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial
23 identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need
24 for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.
25

26
27 ¹ April 7, 2005 FDA Alert: [www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-](http://www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-hcp.htm)
28 [hcp.htm](http://www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-hcp.htm).

1 47. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected
2 “the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1%
3 but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those
4 people taking celecoxib. (p=0.03)”². According to Dr. Sidney Wolfe, “The study revealed a
5 significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the
6 rate of CV deaths in people using celecoxib compared to those using placebo.”³
7

8
9 5. **Cox-2 Studies: VIGOR and APPROVe**

10 48. Pfizer also had access to other data which indicated a cardiovascular risk with its drugs.
11 Specifically, Pfizer had knowledge of two studies conducted by Merck related to its Cox-2 inhibitor
12 Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention
13 (APPROVe).
14

15 a. **VIGOR**

16 49. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR
17 trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.
18

19 50. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research)
20 Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they
21 experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times
22 more edema events, and 1.85 times as many congestive heart failure adverse events. By two measures
23 of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results
24 were considered statistically significant.
25

26
27 ² Public Citizen, January 26, 2005, Dr. Sidney M. Wolfe.

28 ³ Id.

1 51. The VIGOR study comprised the most definitive scientific evidence ever obtained
2 about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical
3 research. It was a safety study with endpoints set in advance. As Merck stated many times, it was
4 designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In
5 medical terms, the VIGOR results raised the question of whether selective inhibition of Cox-2 was a
6 monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes
7 fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs
8 on a daily basis. All makers of NSAIDs, including Defendants, were aware of these results.
9

10
11 **b. APPROVe**

12 52. Anxious to put safety questions surrounding Vioxx to rest, Merck designed another
13 large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's
14 ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to
15 a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data:
16 Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI
17 (myocardial infarction a/k/a heart attack)⁴. *Public Citizen*, January 24, 2005, at 15. Despite the
18 available CELEBREX data and other information related to Vioxx, Pfizer never paused to re-
19 evaluating the CELEBREX data and studies.
20
21

22 53. The scientific data available during and after CELEBREX's approval process made
23 clear to Defendants that their formulation of CELEBREX would cause a higher risk of blood clots,
24
25

26
27 ⁴ Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until
28 after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart
attack was evident in as little as 4 months time.

1 stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to the need to do
2 additional and adequate safety studies.

3 54. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*,
4 outlining Defendants' failure to have conducted the necessary trials before marketing to humans
5 " . . . it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2
6 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease,
7 who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further
8 cardiovascular events."
9

10 55. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed
11 above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2
12 inhibitors.
13

14 56. Based upon readily available scientific data, Defendants knew, or should have known,
15 that their pre-approval testing of CELEBREX did not adequately represent the cross-section of
16 individuals who were intended consumers and therefore, likely to take CELEBREX. Therefore,
17 Defendants' testing and studies were grossly inadequate.
18

19 57. Had Defendants done adequate testing prior to approval and "market launch," rather
20 than the extremely short duration studies done on the small size patient base that was actually done the
21 defendants' scientific data would have revealed significant increases in incidence of strokes and
22 myocardial infarctions among the intended and targeted population of CELEBREX consumers.
23 Adequate testing would have shown that CELEBREX possessed serious side effects. Defendants
24 should have taken appropriate measures to ensure that their defectively designed product would not be
25 placed in the stream of commerce and/or should have provided full and proper warnings accurately
26 and fully reflecting the scope and severity of symptoms of those side effects should have been made.
27
28

1 58. In fact, post-market approval data did reveal increased risks of clotting, stroke and
2 myocardial infarction, but Defendants intentionally suppressed this information in order for them to
3 gain significant profits from continued CELEBREX sales.

4
5 59. Defendants' failure to conduct adequate testing and/or additional testing prior to
6 "market launch" was based upon their desire to generate maximum financial gains for themselves and
7 to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

8 60. At the time Defendants manufactured, advertising, and distributed CELEBREX to
9 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the
10 increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if
11 such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would
12 purchase other cheaper and safer NSAIDs.

13
14 **D. Facts Regarding Defendants' Marketing and Sale of CELEBREX**

15 61. Such an ineffective and unreasonably dangerous drug could only be widely prescribed
16 as a result of a tremendous marketing campaign. In addition to being aggressive, the Defendants'
17 marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising,
18 consumers, including the Plaintiff, would not have purchased CELEBREX, a more costly prescriptive
19 drug, ineffective for its intended purposes.

20
21 62. On January 10, 2005 the FDA issued Pfizer a written reprimand for its promotional
22 activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and 2 Celebrex]
23 variously: omit material facts ... and make misleading safety, unsubstantiated superiority, and
24 unsubstantiated effectiveness claims." This was not the Defendants first offense related to its Cox-2
25 inhibitors. The FDA also reprimanded Pfizer on October 6, 1999 noting: "DDMAC has reviewed
26 these promotional pieces and has determined that they are false or misleading because they contain
27
28

1 unsubstantiated comparative claims, misrepresentations of CELEBREX's safety profile, and are
2 lacking in fair balance." Ultimately, on April 8, 2005, the New York Times reported the results of an
3 FDA advisory panel: "The February advisory panel voted overwhelmingly that the company should
4 never again advertise the drug [CELEBREX]."

6 63. At all times relevant herein, Defendants engaged in a marketing campaign with the
7 intent that consumers would perceive CELEBREX as a safer and better drug than its other NSAIDs
8 and, therefore, purchase CELEBREX.

9 64. Defendants widely and successfully marketed CELEBREX throughout the United
10 States by, among other things, conducting promotional campaigns that misrepresented the efficacy of
11 CELEBREX in order to induce a widespread use and consumption. CELEBREX was represented to
12 aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made
13 misrepresentations by means of media advertisements, and statements contained in sales literature
14 provided to Plaintiff's prescribing physicians.

16 65. Despite knowledge of the dangers presented by CELEBREX, Defendants and
17 Defendants' predecessors in interest, through their officers, directors and managing agents for the
18 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the
19 known defects of Defendants' product, CELEBREX, and failed to warn the public, including Plaintiff,
20 of the serious risk of injury occasioned by the defects inherent in Defendants' product, CELEBREX.
21 Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety
22 testing, and then the manufacturing, sale and marketing of Defendants' product, CELEBREX,
23 knowing that persons would be exposed to serious potential danger, in order to advance their own
24 pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard
25 for the safety of the public and particularly of Plaintiff.
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1 66. In an elaborate and sophisticated manner, Defendants aggressively marketed
2 CELEBREX directly to consumers and medical professionals (including physicians and leading
3 medical scholars) in order to leverage pressure on third party payors, medical care organizations, and
4 large institutional buyers (*e.g.*, hospitals) to include CELEBREX on their formularies. Faced with the
5 increased demand for the drug by consumers and health care professionals that resulted from
6 Defendants' successful advertising and marketing blitz, third party payors were compelled to add
7 CELEBREX to their formularies. Defendants' marketing campaign specifically targeted third party
8 payors, physicians, and consumers, and was designed to convince them of both the therapeutic and
9 economic value of CELEBREX.
10

11 67. Defendants represented that CELEBREX was similar to ibuprofen and naproxen but
12 was superior because it lacked any of the common gastrointestinal adverse side effects associated with
13 these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance, NSAIDS can, in
14 certain patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use.
15 Defendants promoted CELEBREX as a safe and effective alternative that would not have the same
16 deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain
17 relief.
18

19 68. CELEBREX possessed dangerous and concealed or undisclosed side effects, including
20 the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac
21 clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition,
22 CELEBREX was no more effective than traditional and less expensive NSAIDs and, just like
23 traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Defendants
24 chose not to warn about these risks and dangers.
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1 69. Defendants knew of these risks before the U.S. Food and Drug Administration (the
2 “FDA”) approved CELEBREX for sale, but Defendants ignored, downplayed, suppressed, omitted,
3 and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing,
4 and sale of CELEBREX. Defendants’ omission, suppression, and concealment of this important
5 information enabled CELEBREX to be sold to, and purchased, or paid for by, the Consumers at a
6 grossly inflated price.
7

8 70. Consequently, CELEBREX captured a large market share of anti-inflammatory drugs
9 prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded \$2 billion, despite
10 the significantly higher cost of CELEBREX as compared to other pain relievers in the same family of
11 drugs.
12

13 71. Because Defendants engaged in a promotional and marketing campaign that featured an
14 advertising blitz directly targeted to consumers, that touted CELEBREX as a safer drug than other
15 drugs in its class, while uniformly failing to disclose the health risks of CELEBREX, Defendants were
16 able to justify pricing CELEBREX significantly higher than the cost of generic aspirin. In reality, that
17 price inflation was not justified. Had Defendants disclosed the truth about CELEBREX, Defendants
18 would not and could not have reaped the billions of dollars in CELEBREX sales that were achieved as
19 a direct result of the concealment, omission, suppression, and obfuscation of the truth.
20

21 72. The Defendants intentionally, deliberately, knowingly, and actively concealed, omitted,
22 suppressed, and obfuscated important and material information regarding the risks, dangers, defects,
23 and disadvantages of CELEBREX from Plaintiff, the public, the medical community, and the
24 regulators. This concealment and omission was deliberate, knowing, active, and uniform, was
25 intended to induce and maximize sales and purchases of CELEBREX, and prevented Plaintiff from
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1 obtaining all the material information that would be important to their decisions as reasonable persons
2 to purchase, pay for, and/or use CELEBREX.

3 73. Defendants' systematic, active, knowing, deliberate, and uniform concealment,
4 omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use CELEBREX;
5 and caused Plaintiff's losses and damages as asserted herein.
6

7 74. Had Defendants done adequate testing prior to approval and "market launch," the
8 defendants' scientific data would have revealed significant increases in stroke and myocardial
9 infarction amongst the intended population of CELEBREX consumers. Adequate testing would have
10 shown that CELEBREX possessed serious side effects. Defendants should have taken appropriate
11 measures to ensure that their defectively designed product would not be placed in the stream of
12 commerce and/or should have provided full and proper warnings accurately and fully reflecting the
13 scope and severity of symptoms of those side effects should have been made.
14

15 75. In fact, post-market approval data did reveal increased risks of clotting, stroke and
16 myocardial infarction, but Defendants intentionally suppressed this information in order for them to
17 gain significant profits from continued CELEBREX sales.
18

19 76. Defendants' failure to conduct adequate testing and/or additional testing prior to
20 "market launch" was based upon their desire to generate maximum financial gains for themselves and
21 to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.
22

23 77. At the time Defendants manufactured, advertising, and distributed CELEBREX to
24 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the
25 increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if
26 such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would
27 purchase other cheaper and safer NSAID drugs.
28

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

78. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

79. Defendants owed Plaintiffs a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling CELEBREX. This duty included the duty not to introduce a pharmaceutical drug, such as CELEBREX, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

80. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiffs and the Public of the risks, dangers and adverse side effects of their pharmaceutical drug CELEBREX.

81. Defendants breached their duties by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of CELEBREX, including: failing to use due care in the preparation and development of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

a. failing to use due care in the design of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

b. failing to conduct adequate pre-clinical testing and research to determine the safety of CELEBREX;

c. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CELEBREX;

1 d. failing to completely, accurately and in a timely fashion, disclose the results of
2 the pre-marketing testing and post-marketing surveillance and testing to Plaintiffs, consumers, the
3 medical community, and the FDA;

4 e. failing to accompany CELEBREX with proper warnings regarding all possible
5 adverse side effects associated with the use of CELEBREX;

6 f. failing to use due care in the manufacture, inspection, and labeling of
7 CELEBREX to prevent the aforementioned risk of injuries to individuals who used CELEBREX;

8 g. failing to use due care in the promotion of CELEBREX to prevent the
9 aforementioned risk of injuries to individuals when the drugs were ingested;

10 h. failing to use due care in the sale and marketing of CELEBREX to prevent the
11 aforementioned risk of injuries to individuals when the drugs were ingested;

12 i. failing to use due care in the selling of CELEBREX to prevent the
13 aforementioned risk of injuries to individuals when the drugs were ingested;

14 j. failing to provide adequate and accurate training and information to the sales
15 representatives who sold CELEBREX;

16 k. failing to provide adequate and accurate training and information to healthcare
17 providers for the appropriate use of CELEBREX; and

18 l. being otherwise reckless, careless and/or negligent.
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1 82. Despite the fact that Defendants knew or should have known that CELEBREX caused
2 unreasonable and dangerous side effects which many users would be unable to remedy by any means,
3 Defendants continued to promote and market CELEBREX to consumers, including Plaintiffs, when
4 safer and more effective methods of pain relief were available.
5

6 83. Defendants were, or should have been, had they exercised reasonable care, in
7 possession of evidence demonstrating that CELEBREX caused serious side effects. Nevertheless, they
8 continued to market their products by providing false and misleading information with regard to the
9 safety and efficacy of CELEBREX.
10

11 84. Defendants knew or should have known that consumers such as Plaintiffs would
12 foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.
13

14 85. As a direct and proximate consequence of Defendants' acts, omissions, and
15 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs
16 required and will continue to require healthcare and services. Plaintiffs have incurred and will
17 continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to
18 suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a
19 diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and
20 activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical
21 losses and costs include care for hospitalization, physician care, monitoring, treatment, medications,
22 and supplies. Plaintiffs have also suffered loss of wages.
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86. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

87. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CLAIM FOR RELIEF

Strict Liability

88. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

89. At all times relevant to this action, Defendants were suppliers of CELEBREX, placing the drug into the stream of commerce. CELEBREX was expected to and did reach Plaintiffs without substantial change in the condition in which it was manufactured and sold.

90. CELEBREX was unsafe for normal or reasonably anticipated use.

91. CELEBREX was defective in design or formulation because when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect. CELEBREX was also defective and unreasonably dangerous in that the foreseeable risk of injuries from CELEBREX exceeded the benefits associated with the design and/or formulation of the product.

1 92. Celebrex is unreasonably dangerous: a) in construction or composition; b) in design; c)
2 because an adequate warning about the product was not provided; d) because it does not conform to an
3 express warranty of the manufacturer about the product.
4

5 93. The characteristics of Celebrex that render it unreasonably dangerous, existed at the
6 time the product left the control of the manufacturer or resulted from a reasonably anticipated
7 alteration or modification of the product.
8

9 94. The CELEBREX manufactured and supplied by Defendants was also defective due to
10 inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting
11 regarding the results of the clinical trials, testing and study. Defendants failed to perform adequate
12 testing before exposing Plaintiffs to the medication, testing which would have shown that CELEBREX
13 had the potential to cause serious side effects including strokes like that which affected Plaintiffs.
14

15 95. The CELEBREX manufactured and supplied by Defendants was defective due to
16 inadequate post-marketing warnings or instructions because, after Defendants knew or should have
17 known of the risk of injuries from CELEBREX, they failed to provide adequate warnings to the
18 medical community and the consumers, to whom they were directly marketing and advertising
19 CELEBREX; and, further, it continued to affirmatively promote CELEBREX as safe and effective.
20
21

22 96. CELEBREX was manufactured, distributed, tested, sold, marketed, advertised and
23 promoted defectively by Defendants, and as a direct and proximate cause of Defendants' defective
24 design of CELEBREX, Plaintiffs used CELEBREX rather than other safer and cheaper NSAIDs. As a
25 result, Plaintiffs suffered the personal injuries described above.
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1 97. Information given by Defendants to the medical community and to the consumers
2 concerning the safety and efficacy of CELEBREX, especially the information contained in the
3 advertising and promotional materials, did not accurately reflect the potential side effects of
4 CELEBREX.
5

6 98. Had adequate warnings and instructions been provided, Plaintiffs would not have taken
7 CELEBREX as they did, and would not have been at risk of the harmful side effects described herein.
8

9 99. Defendants acted with conscious and deliberate disregard of the foreseeable harm
10 caused by CELEBREX.
11

12 100. Plaintiffs could not, through the exercise of reasonable care, have discovered
13 CELEBREX's defects or perceived the dangers posed by the drug.
14

15 101. As a direct and proximate consequence of Defendants' acts, omissions, and
16 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs
17 required and will continue to require healthcare and services. Plaintiffs have incurred and will
18 continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to
19 suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a
20 diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and
21 activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical
22 losses and costs include care for hospitalization, physician care, monitoring, treatment, medications,
23 and supplies. Plaintiffs have also suffered loss of wages.
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102. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

103. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

THIRD CLAIM FOR RELIEF

Breach of Express Warranty

104. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

105. Defendants expressly represented to Plaintiffs and other consumers and the medical community that CELEBREX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

106. These warranties came in the form of:

a. Defendants' public written and verbal assurances of the safety and efficacy of CELEBREX;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for CELEBREX, which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX, especially to the long-term ingestion of CELEBREX;

c. Verbal and written assurances made by Defendants regarding CELEBREX and downplaying the risk of injuries associated with the drug;

d. False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing CELEBREX during the period of Plaintiffs' ingestion of CELEBREX, and;

e. advertisements.

107. The documents referred to above were created by and at the direction of Defendants.

108. Defendants knew or had reason to know that CELEBREX did not conform to these express representations in that CELEBREX is neither as safe nor as effective as represented, and that CELEBREX produces serious adverse side effects.

109. CELEBREX did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

110. Plaintiffs, other consumers, and the medical community relied upon Defendants' express warranties.

111. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical

1 losses and costs include care for hospitalization, physician care, monitoring, treatment, medications,
2 and supplies. Plaintiffs have also suffered loss of wages.

3
4 112. Defendants' conduct was committed with knowing, conscious, wanton, willful, and
5 deliberate disregard for the value of human life and the rights and safety of consumers, including
6 Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants
7 and deter them from similar conduct in the future.

8
9 113. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory
10 damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys'
11 fees and such other and further relief as this Court deems just and proper.

12
13 **FOURTH CLAIM FOR RELIEF**

14 **Breach of Implied Warranty**

15 114. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully
16 set forth herein and further allege as follows.

17
18 115. Defendants manufactured, distributed, advertised, promoted, and sold CELEBREX.

19
20 116. At all relevant times, Defendants knew of the use for which CELEBREX was intended
21 and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

22
23 117. Defendants were aware that consumers, including Plaintiffs, would use CELEBREX for
24 treatment of pain and inflammation and for other purposes.

25 118. Plaintiffs and the medical community reasonably relied upon Defendants' judgment and
26 expertise to only sell them or allow them to prescribe CELEBREX only if it was indeed of
27 merchantable quality and safe and fit for its intended use. Consumers, including Plaintiffs, and the
28

1 medical community, reasonably relied upon Defendants' implied warranty for CELEBREX.

2
3 119. CELEBREX reached consumers, including Plaintiffs, without substantial change in the
4 condition in which it was manufactured and sold by Defendants.

5
6 120. Defendants breached their implied warranty to consumers, including Plaintiffs;
7 CELEBREX was not of merchantable quality or safe and fit for its intended use.

8
9 121. As a direct and proximate consequence of Defendants' acts, omissions, and
10 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs
11 required and will continue to require healthcare and services. Plaintiffs have incurred and will
12 continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to
13 suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a
14 diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and
15 activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical
16 losses and costs include care for hospitalization, physician care, monitoring, treatment, medications,
17 and supplies. Plaintiffs have also suffered loss of wages.

18
19 122. Defendants' conduct was committed with knowing, conscious, wanton, willful, and
20 deliberate disregard for the value of human life and the rights and safety of consumers, including
21 Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants
22 and deter them from similar conduct in the future.

23
24 123. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory
25 damages and punitive and exemplary damages together with interest, the costs of suit and attorneys'
26 fees, and such other and further relief as this Court deems just and proper.
27
28

FIFTH CLAIM FOR RELIEF

Fraudulent Misrepresentation & Concealment

124. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

125. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of CELEBREX, and their intentional dissemination of promotional and marketing information about CELEBREX for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about CELEBREX's risks and harms to doctors and consumers.

126. Defendants made fraudulent affirmative misrepresentations with respect to CELEBREX in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CELEBREX had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendants represented that CELEBREX was safer than other alternative medications.

127. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of CELEBREX.

128. Defendants made these misrepresentations and actively concealed adverse information

1 at a time when Defendants knew or had reason to know that CELEBREX had defects and was
2 unreasonably dangerous and was not what Defendants had represented to the medical community, the
3 FDA and the consuming public, including Plaintiffs.
4

5 129. Defendants omitted, suppressed and/or concealed material facts concerning the dangers
6 and risk of injuries associated with the use of CELEBREX including, but not limited to, the
7 cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants' purpose was
8 willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of
9 the risks associated with the use of CELEBREX in order to increase its sales.
10

11
12 130. The representations and concealment were undertaken by Defendants with an intent
13 that doctors and patients, including Plaintiffs, rely upon them.
14

15 131. Defendants' representations and concealments were undertaken with the intent of
16 defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and
17 encourage the sale of CELEBREX.
18

19 132. Defendants' fraudulent representations evinced their callous, reckless, willful, and
20 depraved indifference to the health, safety, and welfare of consumers, including Plaintiffs.
21

22 133. Plaintiffs' physician and Plaintiffs relied on and were induced by Defendants'
23 misrepresentations, omissions, and/or active concealment of the dangers of CELEBREX in selecting
24 CELEBREX treatment.
25

26 134. Plaintiffs and the treating medical community did not know that the representations
27 were false and were justified in relying upon Defendants' representations.
28

135. Had Plaintiffs been aware of the increased risk of side effects associated with
CELEBREX and the relative efficacy of CELEBREX compared with other readily available

1 medications, Plaintiffs would not have taken CELEBREX as he did.

2
3 136. As a direct and proximate consequence of Defendants' acts, omissions, and
4 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs
5 required and will continue to require healthcare and services. Plaintiffs have incurred and will
6 continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to
7 suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a
8 diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and
9 activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical
10 losses and costs include care for hospitalization, physician care, monitoring, treatment, medications,
11 and supplies. Plaintiffs have also suffered loss of wages.

12
13
14 137. Defendants' conduct was committed with knowing, conscious, wanton, willful, and
15 deliberate disregard for the value of human life and the rights and safety of consumers, including
16 Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants
17 and deter them from similar conduct in the future.

18
19 138. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory
20 damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys'
21 fees, and such other and further relief as this Court deems just and proper.

22
23 **SIXTH CLAIM FOR RELIEF**

24 **Unjust Enrichment**

25 139. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully
26 set forth herein and further allege as follows.

27 140. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or
28

1 suppliers of CELEBREX.

2 141. Plaintiffs paid for CELEBREX for the purpose of managing their pain safely and
3 effectively.

4 142. Defendants have accepted payment from Plaintiffs for the purchase of CELEBREX.

5 143. Plaintiffs did not receive the safe and effective pharmaceutical product for which she
6 paid.

7 144. It is inequitable and unjust for Defendants to retain this money because Plaintiffs did
8 not in fact receive the product Defendant represented CELEBREX to be.

9
10
11 145. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks equitable
12 relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just
13 and proper.

14
15 **SEVENTH CLAIM FOR RELIEF**
16 **(Wrongful Death)**

17 146. Plaintiff, Cynthia Johnson, incorporates by reference all previous paragraphs of this
18 Complaint as if fully set forth herein.

19 147. As a direct and proximate result of the conduct of Defendants, the breach of implied
20 and expressed warranties, the fraudulent misrepresentations, and/or the defective nature of
21 CELEBREX, as more specifically described herein, Decedent suffered bodily injury and harm,
22 resulting in pain and anguish, and ultimately death. Decedent, and/or those on her behalf, also
23 incurred significant hospital and medical expenses, funeral and administration expenses, loss of
24 earning capacity, shortened life expectancy, and loss of enjoyment of life. Decedent's loved ones also
25 lost the love and affection of having the Decedent in their lives.

26 148. In addition to those other damages detailed above, Plaintiff, Cynthia Johnson, for and
27 on behalf of herself, Decedent, her estate and heirs, and others, seeks recovery of all pecuniary and
28

1 compensatory damages permitted by law which have been incurred or lost as a result of Decedent's
2 death.

3
4 149. Defendants' conduct rose to the level of conscious, wanton, reckless, and intentional
5 disregard for the rights and safety of others, including Decedent.

6
7 150. WHEREFORE, Plaintiff, Cynthia Johnson, for and on behalf of Decedent, demands
8 judgment against Defendants and seeks compensatory damages and punitive and exemplary damages
9 together with interest, the costs of suit and attorneys' fees, and such other and further relief as this
10 Court deems just and proper.

11
12 **EIGHTH CAUSE OF ACTION**

13 **LOSS OF CONSORTIUM**

14
15
16 151. Plaintiff, Cynthia Johnson, repeats and re-alleges each of the allegations contained in
17 this Complaint.

18
19 152. Minnesota law recognizes a spouse's claim for loss of consortium where, due to injury
20 or death, a spouse has been deprived of the services of the other spouse. Loss of consortium
21 encompasses two basic elements of the marital relationship: loss of support and loss of society, which
22 includes companionship. Minnesota law also recognizes a spouse's right to relief for damages
23 occasioned by the death of a spouse. These actions are commonly referred to as survival actions.

24
25 153. At the time of Gregory Johnson's injuries and death, Gregory Johnson and Cynthia
26 Johnson wife/husband, were legally married.

27 154. Due to the injuries and death of Plaintiff's decedent and because of the
28

1 wrongful conduct of Defendants, as more specifically described herein, Plaintiff, Cynthia Johnson has
2 suffered and will continue to suffer the loss of services and consortium of Plaintiff's decedent.
3 Plaintiff, Cynthia Johnson has incurred loss of income, has incurred related expenses, and has suffered
4 extreme emotional and psychological harm.
5

6 155. Defendants' conduct rose to the level of conscious, wanton, reckless, and
7 intentional disregard for the rights and safety of others, including Plaintiff's decedent.
8

9 156. By reason of the foregoing, Plaintiff demands judgment against Defendants
10 and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this
11 Court deems just and proper.
12

13 **PRAYER FOR RELIEF**

14 WHEREFORE, Plaintiffs request the following relief:

- 15 1. General damages in excess of the jurisdictional amount of this Court;
- 16 2. Consequential damages;
- 17 3. Disgorgement of profits;
- 18 4. Restitution;
- 19 5. Damages for loss of consortium, care, comfort, society and companionship in an
20 amount within the jurisdiction of this Court and according to proof;
21
- 22 6. Punitive and exemplary damages;
- 23 7. Pre-judgment and post-judgment interest as provided by law;
- 24 8. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court costs of
25 these causes, and those costs available under the law, as well as expert fees and attorneys' fees and
26 expenses, and costs of this action; and
27
28

9. Such other and further relief as the Court deems just and proper.

Dated: May 10, 2007

Respectively submitted,

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DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all claims so triable in this action.

Dated: May 10, 2007

Respectively submitted,

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